AUG - 3 2006

K061383

510 (K) SUMMARY

510 (K) SUMMARY. SAFETY AND EFFECTIVENESS INFORMATION
BTI DENTAL IMPLANT SYSTEM MODIFICATION

SUBMITTER´S NAME. ADDRESS AND TELEPHONE NUMBER:	B.T.I. Biotechnology Institute, S.L. Parque Tecnológico de Álava Leonardo da Vinci, 14 B Miñano (Álava) **01510 Spain** PH: 34 945 297030 FAX: 34 945 297031
CONTACT PERSON	Leyre Zúñiga Hernando Quality and Regulatory Affairs Pharmacist
SUMARY PREPARATION DATE:	March 2006
ESTABLISHMENT REGISTRATION No:	3004417597
PROPRIETARY NAME:	*Sterile dental drills kit/ Abutments and caps*
COMMON NAME:	Dental bur/ Endosseous dental implant abutment
CLASSIFICATION NAME:	Dental bur (Sec. 872.3240)/ Endosseous dental implant abutment (Sec. 872.3630)
PRODUCT CODE:	EJL/ NHA
DEVICE CLASSIFICATION:	Class I/ II

PREDICATE DEVICE
The modified BTI Dental Implant System is claimed to be substantially equivalent in material, design, and function to BTI Dental Implant System cleared by FDA under 510 (k) K022258 on Sep 11, 2003 and 510 (k) 053355 on Mar 14, 2006.

DEVICE DESCRIPTION

Dental bur are rotary cutting devices intended to cut hard structures in the mouth, such as teeth or bone. They are also intended to cut hard metals, plastics, porcelains, and similar materials intended for use in the fabrication of dental devices.

Endosseous dental implant abutments are premanufactured prosthetic component directly connected to the Endosseous dental implant and are intended for use as aids in prosthetic rehabilitation.

INTENDED USE
BTI Dental Implant System comprising Endosseous titanium implants and prosthetic elements to be attached to the implants, as well as auxiliary elements for surgical and prosthetic procedures.
The intended use of the system is the restoration of missing teeth in partially or fully edentulous patients and/or the fixation of overdentures to restore or enhance the chewing capacity of patients.

Intended use for every modified product:

Dental burs are intended to drill bone tissue and provisionally soft tissues during, before and after a surgical intervention of dental implants.

Endosseous dental implant abutments are intended to model the gingival tissue during the process of healing after the first or second surgery and to be attached to the implant to hold single or multiple teeth restorations.

SUBSTANTIAL EQUIVALENCE
The modified *Sterile dental drills kit, Abutments and caps* are considered to be substantially equivalent to the BTI Dental Implant System.

CONCLUSION
The modified BTI Dental Implant System is considered to be substantially equivalent in design, material and function to BTI Dental Implant System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG - 3 2006

Mr. Leyre Zuniga Hernando
Quality and Regulatory Affairs
B.T.I. Biotechnology Institute, S.L.
Parque Tecnologico de Alava
Leonardo Da Vinci, 14 B
Minano (Alava), Spain 01510

Re: K061383
Trade/Device Name: BTI Sterile Dental Drills Kit/ BTI Abutments and Caps
Regulation Number: 872.3630
Regulation Name: Endosseous Dental Implant Abutment
Regulatory Class: II
Product Code: NHA, EJL
Dated: April 4, 2006
Received: May 18, 2006

Dear Mr. Hernando:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061383

Device Name: BTI *Sterile dental drills kit/ BTI Abutments and caps*

Indications for Use:

Dental burs are intended to drill bone tissue and provisionally soft tissues during, before and after a surgical intervention of dental implants.

Endosseous dental implant abutments are intended to model the gingival tissue during the process of healing after the first or second surgery and to be attached to the implant to hold single or multiple teeth restorations.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner

...an Sign-Off)
...sion of Anesthesiology, General Hospital,
...tion Control, Dental Devices

...) Number K061383